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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,372

06/08/2006

Frank Schilke

4385-053939

9406

28289 7590 12/06/2010  
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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1613

MAIL DATE

DELIVERY MODE

12/06/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/564,372	<b>Applicant(s)</b> SCHILKE ET AL.	
	<b>Examiner</b> BLESSING M. FUBARA	<b>Art Unit</b> 1613	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 23 November 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: \_\_\_\_\_.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 10/28/10 & 11/23/10  
 13. ☐ Other: \_\_\_\_\_.

/Blessing M. Fubara/  
 Primary Examiner, Art Unit 1613

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant has filed WO 00/14128 with the payment of fees after the final rejection; this reference teaches PMAA (page 7, line 20) that contains PHMB (page 8, line 19) and this reference could have been used as art against the claims were prosecution not closed.

The declaration by Frank Schilke on 11/23/2010, which is the content of the remarks on pages 5 of 11 to 10 of 11, is insufficient to overcome the rejection under 35 USC 103(a) of claims 7 and 9-16 based upon Shaffner in view of Fox, Jr and further in view of Nies and Kirschner and the declaration filed on 11/23/20 is also not timely because:

A) the declaration is not timely because the declaration is filed after the close of prosecution and applicant has not provided a showing of good and sufficient reasons why the declaration was not filed before the close of prosecution;

(please note that response to the declaration is also the response to the remarks on pages 5 of 11 to 10 of 11 since the remarks are directed to the declaration) ---

B) The declaration in paragraph 5 compares polyhexamethylene biguanide (PHMB) with gentamicin stating that 0.155% is more effective even after 7 days that amounts of gentamicin greater than 0.86%. This is not persuasive as discussed in paragraphs 25 and 26 of the office action of 8/23/2010; also, the instant specification at page 3 states that 0.155% of PHMB is as effective as 0.86% gentamicin; the prior art do not use gentamicin,

C) The declaration in paragraph 6 states the declarant's expert opinion that the combination of PHMB and PMMA would not have been obvious to a skilled artisan at the time the invention was made to use higher molecular weight PHMB in place of low molecular weight chlorhexidine to achieve the high unexpected antiseptic effectiveness since the use of high molecular weight biguanide contradicts the prevailing opinion that small water soluble molecules are preferred. The examiner disagrees because the opinion has not been substantiated by applicant's specification that a problem existed with delivery of PHMB from solid polymeric carrier materials such as PMMA and the expert opinion in the declaration does not take the place of factual evidence that PHMB is more effective than chlorhexidine; there is also no factual evidence that PHMB at 1% or less acts in synergy with PMMA as antiseptic.

D) The declaration in paragraphs 7-9 state that it would not have been obvious for a person of ordinary skill in the art at the time the invention was made to apply the chlorhexidine of Fox in the bone cement of Shaffner or Nies with the aim of preventing microbial colonization. The examiner disagrees because the goal of Shaffner is to prevent infection in PMMA, chlorhexidine and antibiotic have been known to prevent infection in bone cements and in medical devices.

E) Amendment to the specification to comply with 37 CFR 1.81 is entered; Claim 8 is objected antibiotic is excluded.